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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,679	10/30/2000	Evan C. Unger	UNGR-1598	8248

7590

04/23/2002

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EXAMINER

WILLIS, MICHAEL A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/23/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/699,679

Applicant(s)

UNGER ET AL.

Examiner

Michael A. Willis

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 36-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17:2(a)).
- \* See the attached detailed Office action for a list of the certified copies not-received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                                    |                                                                             |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6,7,8</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election of Group I, claims 1-35 in Paper No. 11, submitted 18 December 2001 is acknowledged. Claims 36-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse.
2. The requirement for restriction is made final.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 2, and 3 are rejected for being vague due to the phrase "lower alkyl" or "lower alkylene". It is unclear how many carbons are contained in a "lower" group.
6. Any remaining claims are rejected for depending from indefinite base claims.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, and 17-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Unger et al (US Pat. 5,830,430). Unger discloses cationic lipids and the use thereof. Compositions of the compounds include liposomes (see abstract). Unger discloses compositions such as Example 5C: a bis hexadecylamino substituted compound (see col. 37, lines 20-45; which appears to be the same compound as Example 1 of the instant application). Lipids, such as dipalmitoylphosphatidylethanolamine-PEG, used in combination with the disclosed compounds are disclosed (see col. 20, line 55 through col. 21, line 40). Gaseous substances such as perfluorobutane are taught (see col. 23, line 22 through col. 24, line 45).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (US Pat. 5,830,430) in view of Unger et al (US Pat. 5,770,222).

12. Unger '430 teaches cationic lipids and the use thereof. Compositions of the compounds include liposomes (see abstract). Unger teaches compositions such as Example 5C: a bis hexadecylamino substituted compound (see col. 37, lines 20-45; which appears to be the same compound as Example 1 of the instant application).

Lipids, such as dipalmitoylphosphatidylethanolamine-PEG, used in combination with the disclosed compounds are taught (see col. 20, line 55 through col. 21, line 40). Gaseous substances such as perfluorobutane are taught (see col. 23, line 22 through col. 24, line 45). The reference lacks the addition of therapeutic agents other than genetic material to the liposomes.

13. Unger '222 teaches therapeutic drug delivery systems. The drug delivery systems include therapeutic agents and liposomes. A variety of therapeutics are taught (see col. 9, line 35 through col. 10, line 62). The liposomes are gas-filled, and provide targeted delivery (see col. 2, lines 10-53).

14. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Unger '430 by the inclusion of a variety of therapeutic agents in order to benefit from the variety of conditions that could be treated as taught by Unger '222.

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**Conclusion**

The elected species of compound of formula IV and compositions comprising the species are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis  
Examiner  
Art Unit 1617

April 22, 2002



MICHAEL G. HARTLEY  
PRIMARY EXAMINER